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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/809,621	06/02/97	IDA N	599-158P

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EXAMINER	
SUN HOFFMAN,L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/09/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/809,621	Applicant(s) Ida et al
	Examiner Lin Sun-Hoffman	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Nov 10, 1998*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *7, 9, 10, and 13-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7, 9, 10, and 13-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Cancellation of claims 11 and 12 is acknowledged. Claims 7, 9-10, 13-15 are pending for the examination.

2. The Modi reference introduced in the office action of 6/10/98 was not necessitated by the amendment; therefore, the finality of the rejection is hereby withdrawn.

Rejection maintained

3. Rejections to claim 7, 9-10 under 35 USC 102 and 103 are maintained.

Claim 7 is amended and drawn to a method for a treating bone disorder comprising administering an effective bone treating an amount of interferon beta or an interferon inducer to a patient suffering from said bone disorder wherein the bone disorder is multiple myeloma or bone metastasis from a tumor selected from the group consisting of mammary carcinoma, lung cancer, prostate cancer, thyroid gland carcinoma, renal cancer, colon cancer, cancer of the digestive tract, and cancer of the esophagus. Claims 9-10 further limit claim 7 in reciting a naturally occurring or recombinant interferon beta; that interferon inducer is interferon alpha, beta or gamma; and the various of bone disorder including osteoporosis.

4. Applicants argue that Gomi reference teaches a method of osteosarcoma, not multiple myeloma or a bone metastasis from other cancers. Applicants further argue that Gomi reference does not teach or suggest that IFN beta affect the proliferation and/or resorption of normal bone cells. Finally, applicants allege that although "ReIFN beta and ReIFN gamma are useful in treating cancers such as osteosarcoma, [it] would not come to the reasonable conclusion that ReIFN-beta or ReIFN-gamma would be useful to treat any and all cancer localized in bone."

Therefore, applicants conclude that aspects of IFN beta or gamma can heal the bone material damaged by cancer and direct treatment of cancers of multiple myeloma, bone metastasis form the difference cancer should be shown by the reference. (See page 5 and 6 of the amendment).

5. Applicants' argument is fully considered but not deemed to be persuasive. First, applicants admitted that osteosarcoma is a bone cancer which falls into the bone disorder; therefore, the imbalance of bone resorption and formation is inherently taught. Second, whether the reference teaches the effect of IFN beta to the proliferation and/or resorption of normal bone cells is irrelevant because it is not within the scope of the claimed invention whereas the claimed invention is about the treatment to the bone disorder resulting from the myeloma or bone metastasis. Thirdly, claims 7, 9-10, 13-15 of treating bone disorder is base on the example of treatment in an osteoporosis animal model (see example 6 of the specification). Other treatment of diseases or bone disorders which potentially known to affect the bone in the claims are based one the obviousness of the enablement of treating osteoporosis. Therefore, if applicants argue about lack of evidence for the rejection of claim 7, i.e., evidence for the treatment of a bone metastasis caused by other cancers or multiple myeloma, the claims in the present invention are thereby not enabled, because applicants have never shown any treatment for these diseases by IFN beta or gamma, including the ones in claim 13-15 (see rejections below) except for osteoporosis.

6. Applicants further argue that Modi et al. do not provide adequate guidance for treating osteoporosis with IFN-beta or IFN-gamma in that it does not include any direction regarding dosage or route of administration. However, absence of the evidence to the contrary, applicant

has the burden to prove that such treatment is not enabled. Therefore, for the same reason set above, Modi reference is applicable to the claims as prior art.

New grounds for rejection necessitated by new claims:

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Modi (US Patent Number 5417982).

Claim 13 and 14 are drawn to a method for treating a bone disorder comprising administering an effective amount of interferon beta or an interferon inducer, wherein the disorder can be osteoporosis.

Modi et al teach a method of treating osteoporosis by interferon beta (see column 4, lines 62-68).

Claims 13-15 are rejected under 35 U.S. C. 102(b) as being anticipated by Michalevicz (U.S. Patent 5,104653) which is necessitated by the amendment to the claims.

Claims 13-15 are drawn to a method for treating a bone disorder wherein the bone disorder is autoimmune disorder and autoimmune disorder is rheumatoid arthritis.

Michalevicz teaches IFN-beta and methods of using IFN beta to stimulate erythropoiesis which occurs in the bones and is therefore broadly defined as a bone disorder. Michalevicz

teaches using IFN beta to treat disorders such as rheumatoid arthritis. (See column 3, lines 44-49).

Claim 13 is rejected under 35 U.S. C. 102(b) as being anticipated by Gomi et al.

Claim 13 is drawn to a method for treating a bone disorder comprising administering an effective bone disorder treating amount of interferon beta or an interferon inducer to a bone disorder, wherein the bone disorder results from a disturbance between the relative balance of bone resorption and bone formation.

Gomi et al teach a method of using IFN-beta to treat human osteosarcoma (see abstract), wherein the osteosarcoma is a malignant neoplasm derived form bone or containing bone tissue. Therefore, the disturbance between the relative balance of bone resorption and bone formation is inherently taught.

Claim Rejections - 35 USC § 103

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gomi et al.

Gomi et al teach a method of using IFN-beta to treat human osteosarcoma (see abstract). However, Gomi et al differ from instant invention in failing to disclose a series of different bone disorders.

It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to use the method of treating bone disorder disclosed by Gomi et al. One of ordinary skill in the art would have been motivated to substitute treatment of bone problems such as bone fracture, osteopetrosis or osteomalacia etc.for Gomi et al's treatment of osteosarcoma by IFN-beta because one of ordinary skill in the art would have recognized that IFN

beta would function in the same manner on all bone tissue related disease in providing a treatment of other bone disorder.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) -308-4301.

Lin Sun-Hoffman, Ph.D.

Dec. 3, 1998

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER